DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004M–0538, 2004M–0495, 2004M–0450, 2004M–0467, 2004M–0471, 2004M–0533, 2004M–0496, 2004M–0497]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

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I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this-30 day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2004, through December 31, 2004. There were no denial actions

during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2004, THROUGH DECEMBER 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P020022/2004M–0538	Bayer Healthcare, LLC	BAYER VERSANT HCV RNA 3.0 ASSAY (bDNA)	March 28, 2003
P020021/2004M–0495	Wilson-Cook Medical, Inc./applicant at approval was Axcan Scandipharm, Inc.	WIZARD X-CELL PHOTODYNAMIC THERAPY BALLOON WITH FIBER OPTIC DIFFUSER	August 1, 2003
P040029/2004M–0450	Szabocsik & Associates	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	September 29, 2004
P030032(S1)/2004M–0467	Genzyme Biosurgery	HYLAFORM PLUS (HYLAN B GEL)	October 13, 2004
P030011/2004M–0471	Syncardia Systems, Inc.	SYNCARDIA TEMPORARY CARDO WEST TOTAL ARTIFICAL HEART (TAH-t)	October 15, 2004
P040002/2004M–0533	Endologix, Inc.	ENDOLOGIX POWERLINK SYSTEM	October 29, 2004
P040022/2004M–0496	Medtronic, Inc./applicant at approval was AngioLink Corp.	EVS VASCULAR CLOSURE SYSTEM	November 3, 2004
P030031/2004M–0497	Biosense Webster, Inc.	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO-COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	November 5, 2004

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: 3/2/05
March 2, 2005.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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